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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,265	10/17/2001	Bo Qiu	271/287	8579

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EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 03/17/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/982,265

Applicant(s)

QIU ET AL.

Examin r

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --
Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

1) The title of the invention and the abstract must be modified to indicate the specific nature of the invention. At a minimum, the title and abstract must indicate that the invention is directed to PEG conjugated to an immunologically reactive substance. The abstract, as currently written, describes "a plurality of copies of an immunologically active molecule". This description is inconsistent with the claims which are directed to "an immunologically reactive substance" coupled to "an immunologically invisible carrier".

2) The specification must be amended to include a section entitled "Brief Description of the Drawings".

3) At page one, lines 8 and 9 of the specification, it is stated that "this application claims priority from" a Qui et al application entitled "Multiple Epitopes Connetnct By A Carrier" (unspecified serial no.). However, both the instant application and the referenced Qui et al application appear to be filed on the same day. Therefore the claim of priority to the Qui et al application appears to be incorrect. Further, the application cannot "claim priority" from published references as set forth at page one, lines 10-13 of the specification.

4) Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

5) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7) Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a kit including a composition comprising a PEG copolymer with the structure depicted in the last structure of Fig. 1 coupled to an epitope does not reasonably provide enablement for all compositions comprised of "an immunologically invisible carrier" coupled an "immunologically reactive substance". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification fails to provide guidance as to what structural and functional moieties would be required of a chemical entity to make it an appropriate "immunologically invisible carrier" and what chemical moieties are required to attach "an immunologically reactive substance" to the carrier.

8) Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the exact chemical structure of the "immunologically invisible carrier" and the points of attachment of the "immunologically reactive substance" and the "reporter moiety" to this carrier.

9) Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) In the use of the words "including" and "comprising" it is unclear what additional components are meant to be incorporated in the kit of claim 1.

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b) In claim 5, it is unclear what is meant by the term "epitope". What are the structural requirements of the "epitope"? Does this term imply a complete antigen or only a fragment thereof?

10) The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11) Claims 1-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 09/982,287 taken alone or in combination with Zalipsky (Bioconjugate Chem. (1995), 6, 150-155). Although the conflicting claims are not identical, they are not patentably distinct from each other because with the open-ended "comprising" terminology used in claim 1 of 09/982,265, the "kit including a composition" is inclusive of the "composition of matter" of claim 1 of 09/982,287. That is, the "immunological test kit including a composition of matter comprising an immunologically reactive substance connected to an immunologically invisible carrier" (09/982,265) is inclusive of "a composition of matter comprising a first immunologically reactive substance connected to a second immunologically reactive substance by an immunologically invisible carrier". The term "comprises" opens claim language to the presence of additional components/moieties in the composition. Further, Zalipsky establishes that PEGs can be conjugated to either one or more biological molecules thus establishing that it would be obvious to attach either one (as in 09/982,265) or more (as in 09/982,287) biomolecules to a PEG linker.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12) Claims 1-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-7 of copending Application No. 09/982,300. Although the conflicting claims are not identical, they are not patentably distinct from each other because the "immunological test kit including a composition of matter comprising an immunologically reactive substance connected to an immunologically invisible carrier" of 09/982,265 is the same as or is inclusive of the "polyethylene glycol copolymer" which is coupled to "an immunologically reactive substance" of claim 2 of 09/982,300. Both the PEG-biomolecule conjugate ("polyethylene glycol copolymer") of claim 2 of 09/982,300 and the "kit including a composition" of claim 1 of 09/982,265 have the same required components, i.e. PEG conjugated to a biomolecule. The "kit" of claim 1 of 09/982,265 requires only a single component: an "immunologically reactive substance connected to an immunologically invisible carrier".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15) Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Zalipsky (Bioconjugate Chem. [1995], 6, 150-165).

Zalipsky describes poly(ethylene glycol) {PEG}, the preferred "immunologically invisible carrier" of the instant invention, attached to "an immunologically reactive substance". These PEG-biomolecule conjugates anticipate the "test kit including a composition of matter" of the instant claims. See Zalipsky, PAGE 150: INTRODUCTION and GENERAL CONSIDERATIONS OF FUNCTIONALIZATION AND CONJUGATION OF PEG; Table 1. Zalipsky specifically addresses the "immunologically invisible" characteristic of the "carrier" of the instant claims in describing PEG as **a)** having a "lack of toxicity and immunogenicity" and as **b)** effecting a decrease in the immunogenicity and antigenicity of proteins upon conjugation to the proteins. The only required component of the "test kit" of the instant claims is the "immunologically reactive substance connected to an immunologically invisible carrier" which moiety is described by Zalipsky.

16) Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zalipsky (Bioconjugate Chem. [1995], 6, 150-165).

Zalipsky is applied for the reason stated in the above rejection made under 35 USC 102(b). The features of the dependent claims are either specifically described by the references (e.g. for specific "immunologically reactive substances", see Table 1 of the reference) or constitute obvious variations in parameters which are routinely modified in the art (e.g. for the choice of attaching an additional "reporter moiety" (claim 8) see the "liposomes" and "particulates" of Table 1 and page 151, first column, first full

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paragraph) and which have not been described as critical to the practice of the invention. The packaging of reagents in kit form is an obvious expedient for ease and convenience in assay performance.

17) Claims 1-7 are rejected under 35 USC 102(b) as being anticipated by Fulton et al (U.S. 4,970,300).

In claim 2, Fulton et al describe a "conjugate" comprised of a "protein" ("an immunologically reactive substance") coupled to a "nonantigenic ligand" defined as "polyethylene glycol" ("an immunologically invisible carrier"); see instant claim 4 wherein PEG is defined as "an immunologically invisible carrier". The "conjugate" of Fulton et al is the same moiety as the sole required component of instant claim 1.

18) Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton et al (U.S. 4,970,300).

The Fulton et al patent is applied for the reason stated in the above rejection made in paragraph **17)**. The packaging of reagents in kit form is an obvious expedient for ease and convenience in administration of a therapeutic composition. See col. 16, "Treatment of Hemophilia" of Fulton et al. The intended use ("immunological test") of instant claim 1 is not a limitation of the composition per se. The products of both the instant claims and Fulton et al are the same.

19) The following references are considered to be cumulative to Zalipsky and Fulton et al (cited above) and are cited to further show the state of the art: Buckmann (Makromol. Chem., 182: 1379-1384 (1981); Zalipsky et al (J. Macromol. Sci.-Chem., A21 (6 & 7): 839-845 (1984)), Geckeler (Polym. Bull, 1: 427-431 (1979)), and Zalipsky et al (Eur. Polym. J., 19: 1177-1183 (1983)).

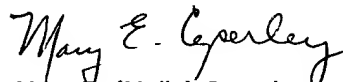
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20) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE** at **(703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

March 13, 2003


Mary E. (Molly) Ceperley
Primary Examiner
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